Docket No.: PF-0293-3 DIV

Response Under 37 C.F.R. 1.116 - Expedited Procedure
Examining Group 1644

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By: _____ Printed: Lyza Finuliar

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Hillman et al.

Title:	HUMAN PEROXISOMAL THIOESTERASE		
Serial No.:	09/766,366	Filing Date:	January 18, 2001
Examiner:	Roark, J.	Group Art Unit:	1644

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BRIEF ON APPEAL

Sir:

Further to the Notice of Appeal filed on August 1, 2003, and received by the USPTO on August 4, 2003, herewith are three copies of Appellants' Brief on Appeal. Appellants hereby request one month extension of time in order to file this Brief. Authorized fees include the statutory fee of $110 for a one-month extension of time, as well as the $ 330.00 fee for the filing of this Brief.

This is an appeal from the decision of the Examiner finally rejecting claims 10, 25, 26, 28, and 30-37 of the above-identified application.

(1) REAL PARTY IN INTEREST

The above-identified application is assigned of record to Incyte Pharmaceuticals, Inc. (now Incyte Corporation, formerly known as Incyte Genomics, Inc.) (Reel 8929 Frame 0266), which is the real party in interest herein.

(2) RELATED APPEALS AND INTERFERENCES

Appellants, their legal representative and the assignee are not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

(3) STATUS OF THE CLAIMS

Claims rejected:	Claims 10, 25-26, 28 and 30-37
Claims allowed:	(none)
Claims canceled:	Claims 1-9, 11-23
Claims withdrawn:	Claims 24, 27, 29 and 38-39
Claims objected to:	Claim 28
Claims on Appeal:	Claims 10, 25-26, 28 and 30-37 (A copy of the claims on appeal, as amended, can be found in the attached Appendix).

(4) STATUS OF AMENDMENTS AFTER FINAL

There were no amendments made after final.

(5) SUMMARY OF THE INVENTION

Embodiments of Appellants' invention are directed to an isolated antibody which specifically binds to a polypeptide, human peroxisomal thioesterase, abbreviated as "PxTE". Appellants' invention includes antibodies which specifically bind PxTE polypeptides comprising the amino acid sequence of SEQ ID NO:1 (See the Specification, e.g., at page 4 lines 9-12 and the Sequence Listing).

As described in the Specification at page 14, lines 8 to 23:

> In one embodiment, the invention encompasses a polypeptide comprising the amino acid sequence of SEQ ID NO:1, as shown in Figs. 1A, 1B, and 1C. PxTE is 311 amino acids in length and has a peroxisomal targeting signal at the C-terminus consisting of residues S 309, K 310 and L 311. As shown in Figs. 2A and 2B, PxTE has chemical and structural homology with TEII from E. coli (GI 147932; SEQ ID NO:3) and CoA thioesterase from yeast (GI 854594; SEQ ID NO:4). In particular, PxTE and E. coli TEII share 44% identity; PxTE and yeast CoA thioesterase share 23% identity. Furthermore, histidine 70 of PxTE aligns with the active-site histidine 58 of E. coli TEII. As illustrated by Figs. 3A and 3B, PxTE and E. coli TEII have rather similar hydrophobicity plots.

Northern analysis shows the expression of this sequence in various libraries, including those prepared from brain and neuronal tissues, colon, small intestine, lung, pancreas, bladder, prostate, breast, uterus, heart, nasal epithelia, and skin; fetal brain, placenta, and thymus; and cell lines derived from promonocytes and mononuclear cells. Of particular note is the expression of PxTE in fetal and cancer-associated tissues, and tissues associated with inflammation, including Crohn's disease-afflicted colon and small intestine, allergy-associated eosinophilic nasal polyp, and erythema nodosum-afflicted skin tissue.

The polypeptides and antibodies of the present invention have a variety of utilities. For example, they can be used in expression profiling, for toxicology testing, for drug discovery, and for the diagnosis, prevention, and treatment of treatment of cancer, inflammation, and disorders associated with fatty acid metabolism. (See the Specification e.g., at page 13, lines 27-30)

(6) ISSUES

1. Whether claim 10, 25-26, 28 and 30-37 are anticipated by Liu et al under 35 U.S.C. §102(a).

2. Whether claim 10, 26, 28 and 33-35 are obvious in view of Liu et al in combination with Zola under 35 U.S.C. §103(a).

3. Whether claim 25, 36 and 37 are obvious in view of Liu et al in combination with Zola and Ramakrishnan et al. under 35 U.S.C. §103(a).

(7) GROUPING OF THE CLAIMS

As to Issue 1

All of the claims on appeal are grouped together.

As to Issue 2

Claims 10, 26, 28, 33-35 are grouped together.

As to Issue 3

Claims 25, 36 and 37 are grouped together.

(8) APPELLANTS' ARGUMENTS

Issue 1 - Rejection under 35 U.S.C. § 102(a)

Claims 10, 26, 28 and 30-32 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Liu et al. (J. Biol. Chem., 272(21): 13779-13785, 1997). In particular, the Examiner has asserted that Liu et al. describes an antisera which would specifically bind to a polypeptide comprising the amino acid sequence of SEQ ID NO:1. Such, however, is not the case.

Liu et al. describes a protein referred to as the thioesterase hTE. The Examiner notes that the Liu hTE protein has 319 amino acid residues, and that residues 19-319 of hTE are identical to residues 11-311 of SEQ ID NO:1 of the present application. The Examiner further notes that Liu et al. described on page 13780, the production of polyclonal antibodies in rabbits by immunization with a synthetic peptide of residues Gly -304 to Lys-318 of hTE. The Examiner concludes that the Liu antisera would "specifically bind to a polypeptide comprising the amino acid sequence of SEQ ID NO:1," and therefore the Liu disclosure anticipates claims 10, 25, 26, 28 and 30-37 of the present application.

The Examiner's incorrect conclusion on anticipation is based on a flawed interpretation of the present claims. Independent claim 10 recites "[a]n isolated antibody which specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:1." The Examiner has ignored the claim recitation of "specifically binds" in applying Liu et al.

It may be that the antisera described by Liu et al. would "bind" a polypeptide comprising SEQ ID NO:1. However, the present claims recite an antibody which "**specifically binds**" a polypeptide comprising SEQ ID NO:1. The ordinary meaning of "specific" is "pertaining to, characterizing, or distinguishing a species." (See the attached dictionary definition of specific).

Thus, an antibody which specifically binds a polypeptide comprising SEQ ID NO:1 will be able to distinguish the SEQ ID NO:1 polypeptide from other polypeptides. The SEQ ID NO:1 amino acid sequence is different from the hTE amino acid sequence described by Liu et al. Hence, the Liu et al. reference antisera does not anticipate the present claims because the Liu et al. antisera binds the hTE protein and, therefore, could not possibly distinguish a polypeptide comprising SEQ ID NO:1 from the hTE protein.

For at least the reasons above, Appellants respectfully request reversal of the §102 rejection.

Issues 2 - Rejection under 35 U.S.C. § 103(a) over Liu et al. in view of Zola.

Claims 10, 26, 28 and 33-35 have been rejection under 35 U.S.C. § 103(a) as being unpatentable over of Liu et al., in view of Zola (Monoclonal Antibodies: A Manual of Techniques, CRC Press, Florida, 1987).

As discussed above, Liu et al. does not teach or suggest an isolated antibody which specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:1. Further, Zola does not correct for this deficiency. Accordingly, reversal of this rejection is respectfully requested.

Issues 3- Rejection under 35 U.S.C. § 103(a) over Liu et al. in view of Zola and Ramakrishnan et al.

Claims 25 and 36-37 have been rejection under 35 U.S.C. § 103(a) as being unpatentable over of Liu et al., in view of Zola and Ramakrishnan et al. (U.S. Patent No. 5,817, 310).

As discussed above, Liu et al. does not teach or suggest an isolated antibody which specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:1. Further, neither Zola nor Ramakrishnan et al. corrects for this deficiency. Accordingly, reversal of this rejection is respectfully requested.

Conclusion

Due to the urgency of this matter and its economic and public health implications, an expedited review of this appeal is earnestly solicited.

If the USPTO determines that any additional fees are due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

This brief is enclosed in triplicate.

Respectfully submitted,

INCYTE CORPORATION

Date: 04 November 2003

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APPENDIX - CLAIMS ON APPEAL

10. An isolated antibody which specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:1.

25. The antibody of claim 10, wherein the antibody is:

(a) a chimeric antibody;

(b) a single chain antibody;

(c) a Fab fragment;

(d) a $F(ab')_2$ fragment; or

(e) a humanized antibody.

26. A composition comprising an antibody of claim 10 and an acceptable excipient.

28. A composition of claim 26, wherein the antibody is labeled.

30. A method of preparing a polyclonal antibody with the specificity of the antibody of claim 10 comprising:

a) immunizing an animal with a polypeptide of SEQ ID NO:1 or an immunogenic fragment thereof under conditions to elicit an antibody response; and

b) screening for antibodies with the polypeptide thereby identifying a polyclonal antibody which binds specifically to a polypeptide of SEQ ID NO:1.

31. An antibody produced by a method of claim 30.

32. A composition comprising the antibody of claim 31 and a suitable carrier.

33. A method of making a monoclonal antibody with the specificity of the antibody of claim 10 comprising:

a) using a polypeptide of SEQ ID NO:1, or an immunogenic fragment thereof, to make antibody-producing hybridoma cells; and

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34. A monoclonal antibody produced by a method of claim 33.

35. A composition comprising the antibody of claim 34 and a suitable carrier.

36. The antibody of claim 10, wherein the antibody is produced by screening a Fab expression library.

37. The antibody of claim 10, wherein the antibody is produced by screening a recombinant immunoglobulin library.

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